

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-R-0013

FORM APPROVED  
OMB NO. 0579-0036

CUSTOMER NUMBER: 76

SEP 22 2005

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Cytimmune Sciences, Inc.

~~8075 Greenmead Drive~~

~~College Park, MD 20740~~

9640 Medical Center Dr  
Rockville, MD 20850

Telephone:

(b)(6), (b)(7)c

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		4		1	5
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS:**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

(b)(6), (b)(7)c

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

(b)(6), (b)(7)c

DATE SIGNED

11/30/05

Q92

## Column E Explanation

DEC 01 2005

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-R-0013

2. Number 1 of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

4. Explain the procedure producing pain and/or distress.

The procedure that caused unrelieved pain and/or distress was the subcutaneous injection of Freund's complete adjuvant. The subcutaneous injection of Freund's complete adjuvant is used to induce a robust immune response as the initial treatment in an IACUC approved protocol for the production of polyclonal antibodies in rabbits. Clinically, the rabbit did not develop an abscess, lesion or any other skin irritation. The subcutaneous injection was well tolerated and no long-term effects were noted.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Scientifically, inducing a local inflammatory response is a critical first step in the production of a specific polyclonal antibody. Absent such a stimulus, it is unlikely that the animal's immune system would see the desired antigen as foreign and respond to it by producing an antibody. The Freund's complete adjuvant provides such an initial stimulus, and is used just once. Subsequent injections are given in Freund's incomplete adjuvant, which does not induce a local inflammatory response, similar to Freund's complete adjuvant. Consequently, any procedure that would reduce the local immune response induced by the injection of Freund's complete adjuvant would make the production of the specific antibody needed for our research project near to impossible.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

Facilities Statement for CytImmune Sciences, Inc.

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Registration Number: 51-R-0013

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CytImmune Sciences, Inc.'s rabbits are housed in the

(b)(2)High, (b)(7)f